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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,297	11/02/2001	Jeff G. Hall	FORS-06675	1030
7590 01/11/2005 MEDLEN & CARROLL, LLP Suite 350 101 Howard Street San Francisco, CA 94105			EXAMINER LU, FRANK WEI MIN	
			ART UNIT 1634	PAPER NUMBER

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/033,297	Applicant(s) HALL ET AL.	
	Examiner Frank W Lu	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on October 25, 2004 has been entered. The claims pending in this application are claims 35 and 47. Rejection and/ or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on October 25, 2004.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 35 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To the extent that the claimed methods are not described in the instant disclosure, claims 35 and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

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The recitation “an incomplete cleavage structure” and “the signal exhibits a specific behavior as a function of time, wherein said specific behavior as a function of time is non-linear, and wherein said signal that exhibits said specific behavior as a function of time is indicative of the presence of said target nucleic acid” are in the newly amended independent claim 35.

Although the specification describes “cleavage structure” (e.g., see page 112, second paragraph) and describes a formula for simple invasive cleavage reaction (e.g., see page 112, last paragraph bridging to page 113, first paragraph), the specification fails to define or provide any disclosure to support the phrases “an incomplete cleavage structure” in ii) of claim 35 and “the signal exhibits a specific behavior as a function of time wherein said specific behavior as a function of time is non-linear, and wherein said signal that exhibits said specific behavior as a function of time is indicative of the presence of said target nucleic acid” in step c) of claim 35.

MPEP 2163.06 notes “If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.” (emphasis added).

Response to Arguments

In page 9, last paragraph bridging to page 10, second paragraph of applicant’s remarks, applicant argues that: (1) the statement “to complete a cleavage structure to enable a secondary invasive cleavage reaction” in the specification, page 112, lines 11-14, and Figure 96 supports the phrase “an incomplete cleavage structure”; and (2) the specification, page 112, line 28 to page 113, line 7 and page 117, line 28 to page 118, line 2 support the phrase “the signal exhibits

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a specific behavior as a function of time, wherein said specific behavior as a function of time is non-linear, and wherein said signal that exhibits said specific behavior as a function of time is indicative of the presence of said target nucleic acid”.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, although the specification describes “cleavage structure” (see page 112, second paragraph), the specification does not describe “an incomplete cleavage structure”. Second, although the specification describes a formula for simple invasive cleavage reaction (see page 112, last paragraph bridging to page 113, first paragraph), the specification fails to define or provide any disclosure to support the phrases “an incomplete cleavage structure” in ii) of claim 35 and “the signal exhibits a specific behavior as a function of time wherein said specific behavior as a function of time is non-linear, and wherein said signal that exhibits said specific behavior as a function of time is indicative of the presence of said target nucleic acid”.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 35 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 35 is rejected as vague and indefinite in view of the phrase “the cleaved unpaired region of the probe oligonucleotide and the reagent can come into contact with an incomplete cleavage structure, to which the unpaired region of the probe oligonucleotide is capable of

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hybridizing to form a complex that can be, cleaved by the reagent to provide a product capable of being detected” because, if a complex formed by the unpaired region of the probe oligonucleotide and an incomplete cleavage structure can be cleaved by the reagent, how the unpaired region of the probe oligonucleotide and an incomplete cleavage structure can form a complex in the presence of the reagent. Therefore, the first part of the phrase and the second part of the phrase do not correspond each other. Please clarify.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. No claim is allowed.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of

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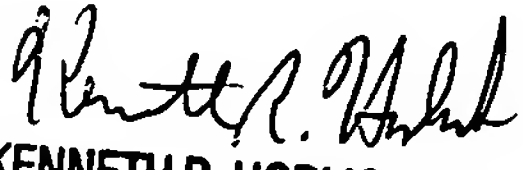
such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
January 3, 2005


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

1/5/05